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| Notice of Allowability | Application No. | Applicant(s) |
| | 10/019,396 | NAGATA, RYOICHI |
| | Examiner | Art Unit |
| | Humera N. Sheikh | 1615 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTO-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. This communication is responsive to 31 January 2005.
2. The allowed claim(s) is/are 1,2,5,7,9,10,15 and 16.
3. The drawings filed on 28 December 2001 are accepted by the Examiner.
4. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some* c) None of the:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 1) hereto or 2) to Paper No./Mail Date _____.
 - (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of
 Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
7. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. Notice of References Cited (PTO-892)
2. Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. Information Disclosure Statements (PTO-1449 or PTO/SB/08),
 Paper No./Mail Date _____
4. Examiner's Comment Regarding Requirement for Deposit
 of Biological Material
5. Notice of Informal Patent Application (PTO-152)
6. Interview Summary (PTO-413),
 Paper No./Mail Date 2/28/05
7. Examiner's Amendment/Comment
8. Examiner's Statement of Reasons for Allowance
9. Other _____.

[Signature]
THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

DETAILED ACTION

Status of the Application

Receipt of the Amendment after Final Arguments/Remarks and the request for extension of time (2 months-granted), both filed 01/31/05 is acknowledged.

Claims 1, 2, 5, 7 and 9-12 are pending. Upon entry of the Examiner's Amendment, Claims 1, 2, 5, 7, 9, 10, 15 and 16 will be pending. Claims 11 and 12 will be cancelled. New claims 15 and 16 will have been added. Claims 3, 4, 6 and 8 have previously been cancelled. Claims 1, 2, 5, 7, 9, 10, 15 and 16 are allowed.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Matthew M. Jacob on 02/25/05.

The application has been amended as follows:

In the Claims:

New claims 15 and 16 have been added.

Claims 11 and 12 have been cancelled.

15. (New) A method for the treatment of diabetes that comprises administering the formulation of Claim 1 into the nasal cavities of diabetics who need an effective amount of insulin.

16. (New) The method according to Claim 15, in which the calcium carbonate is substantially composed of cubic or trigonal system crystals with a particle diameter in the range of 20-32 μm , and the insulin content of a combined component of insulin and calcium carbonate is 0.1-50% by weight based on the total weight of the component.

Allowable Subject Matter

Claims 1, 2, 5, 7, 9, 10, 15 and 16 are allowed.

The following is an examiner's statement of reasons for allowance:

The primary reasons for allowance are that the prior art (Yanagawa US 6,197,328 & Yanagawa EPO 0 681 833 A2) do not disclose nor fairly suggest a formulation for the nasal absorption of insulin comprising porous spherical calcium carbonate having a relative surface area of $1.5 \text{ m}^2/\text{g}$ or greater. Rather, the prior art teaches calcium carbonate having a surface area from $0.1 \text{ m}^2/\text{g}$ to $0.4 \text{ m}^2/\text{g}$. The instant surface area claimed of $1.5 \text{ m}^2/\text{g}$ or greater provides for improved and excellent effects for nasal absorption of medicines, such as insulin and does not require using an absorption accelerator, as does the prior art. The surface area claimed by

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Applicant ($1.5 \text{ m}^2/\text{g}$ or greater) provides for greater Cmax ($\mu\text{U/mL}$) levels of medicine, not achieved by the prior art formulations. For instance, as seen in the Declaration of Dr. Shunji Haruta filed 5/11/04, the instant invention, which provides for a carrier of calcium carbonate alone, achieves about 5.7 times or even about 11.9 times as high a Cmax ($\mu\text{U/mL}$) as compared with that of the prior art (Yangagawa's) formulation. Additionally, the prior art fails to teach a porous, spherical calcium carbonate as claimed. The calcium carbonate employed in the present invention is a porous, spherical calcium carbonate, which has a special particulate structure as compared with the regular calcium carbonate employed in the art. Due to the instant porous, spherical calcium carbonate's special particulate structure, a greater improvement in achieving serum concentration of insulin is obtained. For these reasons, the instant invention is rendered non-obvious and patentable over the cited prior art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H. N. Sheikh 

Patent Examiner

Art Unit 1615

February 28, 2005


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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